

# MINULET<sup>®</sup> TABLET

Gestodene/Ethinyl estradiol (75 mcg/30 mcg)

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## What MINULET is used for

MINULET is an oral contraceptive or birth control pill and is used to prevent pregnancy.

## How MINULET works

MINULET contains two hormones (gestodene and ethinyl estradiol), which are similar to the hormones that your body normally produces. If taken correctly, MINULET prevents you from becoming pregnant in several ways:

- It inhibits the egg from maturing and stopping it from being released.

## Before you use MINULET

### - When you must not use it

Do not take MINULET

- If you are allergic to gestodene, ethinyl estradiol or any of the ingredients of MINULET.
- If you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.
- If you have or have had a blood clot disorder.
- If you have disease related to the blood vessels in the brain or heart.
- If you have uncontrolled high blood pressure.
- If you have diabetes with blood vessel damage.
- If you have headache with aura (sensitivity to light and sound).
- If you are pregnant or think you might be pregnant.
- If you have or have had liver cancer (tumour) or disease.
- If you have vaginal bleeding of unknown cause.

- If you have any other inherited bleeding disorder.
- If you have or are suspected of having breast cancer or cancer that is sensitive to female sex hormones.
- If you have or known to have had inflammation of the pancreas, which is associated with very high blood levels of triglycerides (fatty substances).

## *Pregnancy and lactation*

If you become pregnant while taking MINULET, stop taking the pill and consult your doctor.

If you are planning a pregnancy, tell your doctor.

Few side effects on the child have been reported, including jaundice and breast enlargement.

It is not recommended to use MINULET if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

MINULET may reduce the quantity and change the composition of breast milk.

### - Before you start to use it

Tell your doctor if:

- you smoke. The risk of serious side effects on the heart and blood vessels is even greater if you smoke and take oral contraceptives. The risk increases with age and with heavy smoking (15 or more cigarettes per day), especially in women older than 35 years. If you take MINULET, you should not smoke.
- you have had blood clots in the blood vessels, a stroke or heart attack or you have any of the following conditions:
  - recent surgery or trauma
  - recently had a baby
  - lost a baby in the second trimester
  - confined to bed rest for long periods
  - smoking

- high blood pressure
- high cholesterol
- obesity
- increasing age
- you have gallbladder disease
- you have migraine or other headaches
- you have hereditary angioedema. Medicines containing oestrogens may induce or worsen symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, arms, legs, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing
- you have diabetes or impaired glucose tolerance
- you have high level of cholesterol and fats
- you have a history of depression

MINULET and cancer: Breast cancer has been detected more often in women using combination pills, but it is not known whether this is caused by the pill. It is possible that these women were simply examined more thoroughly and more frequently, meaning that the breast cancer was detected earlier.

In women using combination pills for a relatively long time, studies have reported cases of cervical cancer. It is currently unknown whether it is caused by the pill or connected with sexual behaviour and other factors.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users.

You must have a thorough medical check-up, including a Pap smear blood pressure check, examination of breast, liver and pelvis.

MINULET is not for use in children or in post-menopausal women. This product does not protect you against HIV infection (AIDS) or other sexually transmitted diseases.

### - Taking other medicines

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Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Do not take MINULET if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products.

Tell your doctor if you are taking

- medicines used for treatment of HIV infections (such as indinavir);
- medicines used for treatment of epilepsy and other conditions (phenytoin, primidone, topiramate, barbiturates and lamotrigine);
- medicines used for treatment of tuberculosis (such as rifabutin, rifampicin);
- antibiotics (such as ampicillin, troleandomycin, other penicillin or tetracycline);
- antifungal agents (such as griseofulvin, fluconazole);
- theophylline (used for asthma and other breathing difficulties);
- medicines used to treat certain types of depression (such as St. John's wort);
- medicines used for pain relief and reducing fever (such as paracetamol and phenylbutazone);
- flunarizine (used to prevent migraine headaches);
- cyclosporine (used to prevent organ rejection);
- medicines used to reduce inflammation (corticosteroids such as dexamethasone);
- atorvastatin (used to treat high cholesterol);
- modafinil (used to treat excessive daytime sleepiness);
- ascorbic acid (Vitamin C).

If you are scheduled for any laboratory tests, tell your doctor you are taking MINULET. Some blood tests may be affected by taking MINULET.

## How to use MINULET

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Tablets must be taken in the order directed on the package every day at the same time. One tablet is to be taken daily for 21 consecutive days followed by a 7-day tablet-free interval. Each subsequent pack is started on the day after the tablet-free interval. A withdrawal bleeding usually starts on days 2-3, after the last tablet, and may not have finished before the next pack is started.

### **If you have not used a contraceptive with hormones in the previous month:**

Start taking MINULET on the first day of your period. You can also start MINULET on days 2-7 of the menstrual cycle (e.g., Sunday start), but you should use another method of contraception as well, such as condom, for the first seven pill-taking days.

### **If you are changing from another contraceptive pill:**

Finish the pack you are on (if your present pill pack also contains hormone-free tablets, do not take them). Then start the MINULET pack the next day without leaving any pill-free break. You can also start the MINULET pack no later than the day following the usual tablet-free or inactive tablet interval of the previous contraceptive pill.

### **If you were using a progestin-only method (progestin-only pill, an injectable method or an implant/intrauterine device [IUD]):**

- changing from a progestin-only pill: you can stop the progestin-only pill at any time and start MINULET the next day;

- changing from an implant/IUD: start MINULET the day the implant/IUD is removed;
- changing from an injectable contraceptive: start MINULET on the day your next injection was due.

In all cases you must use a non-hormonal contraceptive method (for example: a condom) during the first 7 days of taking MINULET.

### **If you are starting MINULET after a termination of pregnancy that occurred during the first trimester:**

You can normally start immediately, but should follow the advice of your doctor before doing so.

### **After having a baby or after a termination of pregnancy that occurred during the second trimester:**

If you have just had a baby, talk to your doctor before you start taking MINULET. You can start taking MINULET after 28 days from the time of childbirth or termination of pregnancy in second trimester. You should be advised to use an additional, non-hormonal contraceptive as backup for the first seven days of taking MINULET. If you have had unprotected sex, pregnancy should be ruled out or wait until you get your next period before beginning use of MINULET.

**If you want to delay your period,** you should continue the next pack of MINULET after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second new blister pack. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of MINULET should be resumed after the usual 7 days tablet-free interval.

**If you get vomiting or diarrhea within 4 hours after taking the tablet,** it may not work. Use of tablets from a back-up pack is required.

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## - When to use it

Use as directed by your doctor or pharmacist.

MINULET will work best if you do not miss any tablets and take it at the same time each day. Taking your tablet at the same time each day will also help you to remember when to take the tablets.

## - How long to use it

Continue taking MINULET for as long as your doctor recommends.

## - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you forget to take a tablet there is a risk you could become pregnant.
- If you forget one MINULET tablet but it is less than 12 hours late, take the missed tablet immediately. Take the next tablet at your usual time.
- If one MINULET tablet is missed and is more than 12 hours late or two or more tablets are missed, your contraceptive protection may be lower so you must use extra protection. Take the last missed tablet as soon as you remember even if this means taking two tablets in one day. Continue to take tablets at your usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) for the next 7 days.

## - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain,

drowsiness/fatigue and sometime withdrawal bleeding may occur in some cases.

## **While you are using it**

### - Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking MINULET.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give MINULET to anyone else, even if it is for the same intention.

### - Things to be careful of

#### *Driving and using machines*

MINULET is not expected to influence the ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Sometimes withdrawal bleeding may not occur during the tablet free interval. If you have not taken MINULET according to directions prior to the first missed withdrawal bleed, or if two consecutive withdrawal bleeds are missed discontinue the medicine. You may have to use another method of birth control until the possibility of pregnancy is excluded.

Breakthrough bleeding or spotting persists or recurs after three months also, adequate diagnostic measures should be taken to rule out pregnancy, infection, malignancy, or other conditions.

## **Side effects**

Like all medicines, MINULET can cause

side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

## **Very common side effects**

- Headache, including migraines
- Breakthrough bleeding or spotting

## **Common side effects**

- Inflammation of vagina resulting in discharge, itching and pain, vaginal thrush (candida)
- Mood changes, including depression, changes in sex drive
- Nervousness, dizziness
- Nausea; vomiting; stomach pain
- Acne
- Painful periods, missed periods, changes in bleeding patterns
- Changes in the cervix (lower part of the womb) resulting in light mucous discharge, pain and bleeding during and after intercourse, breast pain, tenderness, enlargement, possible milk secretion;
- Weight change
- Fluid retention/swelling

Reasons for Immediate Discontinuation of MINULET:

1. The occurrence for the first time of migrainous headaches or the more frequent occurrence of unusually severe headaches.
2. Sudden change of vision, hearing or other perceptual disorders.
3. First symptoms of blood clots in the blood vessels.
4. Development of yellowing of the whites of the eyes or of the skin (jaundice), liver inflammation or generalized itching.
5. Increase in fits.
6. Significant rise in blood pressure.
7. Pregnancy.
8. Four weeks prior to and for two weeks after elective surgery.
9. During prolonged immobilization.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the [npra.gov.my](http://npra.gov.my) [Consumers→Reporting

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Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

W12 HX57,  
Ireland

## Storage and Disposal of MINULET

### - Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in a cool, dry place.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.  
Level 10 & 11  
Wisma Averis, Tower 2  
Avenue 5, Bangsar South  
No. 8, Jalan Kerinchi  
59200 Kuala Lumpur, Malaysia

## Date of Revision

12/03/2025

## Serial Number

NPRA(R2/1)211224/815

**PLD-MINULET-0325**

## Product Description

### - What it looks like

White, sugar coated tablet with a shiny surface. Each MINULET package contains 21 tablets.

### - Ingredients

#### • Active ingredient

75 mcg Gestodene and 30 mcg  
Ethinyl estradiol

#### • Inactive ingredients

##### Tablet core:

Sodium Calcium Edetate, Lactose  
Hydrous EP 80 Mesh, Starch Maize  
EP, Povidone EP K-25, Magnesium  
Stearate.

##### Tablet coating:

Sucrose Granular EP, Povidone EP  
K-90, Polyethylene Glycol 6000  
powder, Calcium Carbonate Light  
EP, Talc, Wax E Pharma.

### - MAL number

MAL19991384AZ

## Manufacturer

Pfizer Ireland Pharmaceuticals Unlimited  
Company,  
Little Connell, Newbridge,

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